

REMARKS

Upon entry of the present amendment, claims 1 – 4, 6, 7, 11, 14 – 19, 21 – 26, and 29 – 31 are pending. Claims 5, 8 - 10, 12, 13, 20, 27, 28 and 32 – 37 have been cancelled. Claim 1 has been amended to now recite the further limitation of “wherein said composition has decreased formation of heavy chain fragments upon storage of said aqueous composition for 6 months at 2-8°C as compared with non-hypertonic compositions. Basis for the amendment can be found in the Specification as originally filed, and in particular in Examples 7 and 9. The present amendment adds no new matter.

THE 35 U.S.C. §103(A) REJECTION

The Examiner has rejected claims 1-4, 6-7, 10-19, 21-26 and 29-31 under 35 U.S.C. 103(a) as being unpatentable over The Medicine Catalogue (“**The Medicine Catalogue**”) in view of Pingel *et al.* (US Patent No. 6,903,069; “**Pingel**”) and Johannessen *et al.* (WO 01/82943; “**Johannessen**”).

Applicants again note that the present invention is based on the discovery that such “*hypertonic*” compositions dramatically result in a decreased formation of heavy chain fragments during storage for as long as six months. *See e.g.* Examples 7 and 9. For instance, such “*hypertonic*” compositions have over 50% less heavy chain fragments form than compositions as such those taught in the art (*i.e.* those having approximately 1.5 mg/ml of CaCl₂; composition 1 of Example 7 and formulation A of Example 9). In contrast, the compositions taught in both **The Medicine Catalogue** and **Johannessen** do not teach or suggest that a composition where the amount CaCl₂ was optimized to anywhere near the amount in the present invention (29.4 mg/ml of CaCl₂). One skilled in the art would not be motivated to raise the amount of CaCl₂ to the levels claimed herein because the prior art teaches that levels as low as 1.0 mg/ml (**Johannessen**) or 1.5 mg/ml (**The Medicine Catalogue**) were sufficient to maintain FVIIa activity. Thus, Applicants assert that the prior art actually *teaches away from* optimizing compositions using more CaCl₂, but instead lead those skilled in the art that satisfactory results are obtained at lower levels of CaCl₂.

However, in order to expedite allowance of the present Application, Applicants have amended claim 1 to more clearly recite the metes and bounds of the present invention. Specifically, Applicants have amended claim 1 to now recite the further limitation of “wherein said composition has decreased formation of heavy chain fragments upon storage of said aqueous composition for 6

months at 2-8°C as compared with non-hypertonic compositions. Basis for the amendment can be found in the Specification as originally filed, and in particular in Examples 7 and 9. Accordingly, in light of the amendment and arguments above, Applicants request reconsideration and withdrawal of the present invention.

THE NON-STATUTORY DOUBLE PATENTING REJECTION

The Examiner has rejected claims 1 – 4, 6, 7, 11, 14-19, 21 – 26 and 29 – 31 on the grounds of non-statutory obviousness-type double patenting as being unpatentable over claims 1 – 10 of U.S. Patent No. 6,833,352.

Upon notification of allowable subject matter, Applicants will file all necessary Terminal Disclaimers.

Conclusion

In view of the above, Applicant(s) submit(s) that the application is now in condition for allowance and issue and respectfully request(s) early action to that end. Applicant(s) believe(s) that no additional fees are due. However, should any fees be due, the Commissioner is hereby authorized to charge any fees in connection with this application and to credit any overpayments to Deposit Account No. 14-1447. The undersigned invites the Examiner to contact her by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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/Shelby J. Walker, Reg. No. 45,192/
Shelby J. Walker, Reg. No. 45,192
Novo Nordisk Inc.
Customer Number 23650
(609) 987-4883